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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,913	05/13/2002	Michael G Walker	PB-0005 USN	5286

7590 12/15/2004  
Incyte Genomics Inc  
Legal Department  
3160 Porter Drive  
Palo Alto, CA 94304

EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/830,913

Applicant(s)

WALKER ET AL.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-14 are currently pending in the application and are addressed herein.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 5-7, drawn to a substantially purified polynucleotide that is SEQ ID NO:1.

Group II, claim(s) 1, 2, 5-7, drawn to a substantially purified polynucleotide that is SEQ ID NO:2.

Group III, claim(s) 1, 2, 5-7, drawn to a substantially purified polynucleotide that is SEQ ID NO:3.

Group IV, claim(s) 1, 2, 5-7, drawn to a substantially purified polynucleotide that is SEQ ID NO:4.

Group V, claim(s) 1, 2, 5-7, drawn to a substantially purified polynucleotide that is SEQ ID NO:5.

Group VI, claim(s) 1, 2, 5-7, drawn to a substantially purified polynucleotide that is SEQ ID NO:6.

Group VII, claim(s) 1, 2, 5-7, drawn to a substantially purified polynucleotide that is SEQ ID NO:7.

Group VIII, claim(s) 1, 2, 5-7, drawn to a substantially purified polynucleotide that encodes SEQ ID NO:8.

Group IX, claim(s) 1, 2, 5-7, drawn to a substantially purified polynucleotide that encodes SEQ ID NO:9.

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Group X, claim(s) 3, 4, 7, drawn to a substantially purified polypeptide that is SEQ ID NO: 8.

Group XI, claim(s) 3, 4, 7, drawn to a substantially purified polypeptide that is SEQ ID NO: 9.

Group XII, claim(s) 3, 4, 7, drawn to an antibody that specifically binds to the polypeptide that is SEQ ID NO: 8.

Group XIII, claim(s) 3, 4, 7, drawn to an antibody that specifically binds to the polypeptide that is SEQ ID NO: 9.

Group XIV-XXII, claim(s) 9, drawn to a method for diagnosing a disease comprising hybridizing a polynucleotide that is any ONE (1) of SEQ ID Nos: 1-7, a polynucleotide encoding SEQ ID NO: 8 or a polynucleotide encoding SEQ ID NO:9; wherein Groups XIV-XXII correspond to using SEQ ID Nos: 1-9, respectively (i.e., Group XIV encompasses SEQ ID NO:1, Group XV encompasses SEQ ID NO:2, etc). NOTE: this is not a species election, rather each sequence (i.e., SEQ ID NO) is a distinct group.

Groups XXIII-XXIV, claim(s) 10 and 12, drawn to a method for treating or preventing a disease comprising administering any ONE (1) of the polynucleotides that is SEQ ID Nos. 1-7 (Groups XXIII-XXIV, respectively). NOTE: this is not a species election, rather each sequence (i.e., SEQ ID NO) is a distinct group.

Groups XXX-XXXI, claim(s) 10, drawn to a method for treating or preventing a disease comprising administering any ONE (1) of the polynucleotides encoding SEQ ID Nos. 8-9 (Groups XXX-XXXI, respectively). NOTE: this is not a species election, rather each sequence (i.e., SEQ ID NO) is a distinct group.

Groups XXXII-XXXIII, claim(s) 11, drawn to a method for treating or preventing a disease comprising administering an antibody that binds to any ONE (1) of the polypeptides of SEQ ID 8-9, respectively. NOTE: this is not a species election, rather each sequence (i.e., SEQ ID NO) is a distinct group.

Groups XXXIV-XLII, claim(s) 13, drawn to a ribozyme that cleaves any ONE (1) polynucleotide associated with SEQ ID Nos: 1-9, respectively. NOTE: this is not a species election, rather each sequence (i.e., SEQ ID NO) is a distinct group.

Groups XLIII-LII, claim(s) 14, drawn to a method using a ribozyme that cleaves any ONE (1) polynucleotide associated with SEQ ID Nos: 1-9, respectively. NOTE: this is not a species election, rather each sequence (i.e., SEQ ID NO) is a distinct group.

The inventions listed as Groups I-LII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In order for a technical feature to be a special

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technical feature, it MUST be novel. In the instant case, the inventions are related by the technical feature that is polynucleotide that encodes a gene that is coexpressed with one or more known corticosteroid synthesis genes, as indicated in claim 1. However, this technical feature is not a special technical feature because it is not novel. Specifically, WO 94/29434 (UNIV CALIFORNIA) teaches such a polynucleotide, as indicated in the International Search Report (i.e., it is cited as an "X" reference). Therefore, there is no special technical feature linking the inventions and the restriction is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

steroid acute regulatory gene  
P450scc cholesterol side-chain cleavage enzyme  
3-beta-hydroxysteroid dehydrogenase,  
Type I 3-beta-hydroxysteroid dehydrogenase,  
Type 11 3-beta-hydroxysteroid dehydrogenase,  
P450c11 beta-hydroxylase  
P450c17 alpha-hydroxylase.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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The following claim(s) are generic: 1, 3, 9-12 and 14.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: In order for a technical feature to be a special technical feature, it MUST be novel. In the instant case, the species are not novel and where well known in the art. Since the species are not novel, there is no special technical feature linking the species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

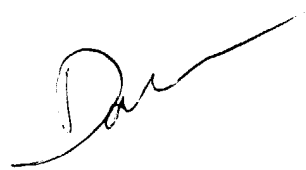
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.  
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A handwritten signature in black ink, appearing to read "Jon Eric Angell", with a long, sweeping horizontal line extending to the right.A faint, illegible handwritten mark or signature in light gray or blue ink, located below the main signature.